The information contained in this template letter is provided by Acerus to physicians for convenience and informational purposes only. Acerus is not making any medical claims in this template. There is no requirement that any patient or healthcare provider use any Acerus product in exchange for this information, and this template letter is not meant to substitute for a prescriber’s independent medical decision-making.

[Physician letterhead] [Date]

[Appeals department]

[Name of health plan] [Mailing address]

RE: [Patient name]

Policy number: [Policy number] Claim number: [Claim number]

Subject: Supporting coverage of NATESTO® (testosterone) Nasal Gel, CIII, 5.5 mg/actuation

Dear [Medical director],

This letter is sent on behalf of [patient’s name] to document that he has been diagnosed with [testosterone deficiency/hypogonadism] and requires treatment with NATESTO® (testosterone) Nasal Gel for managing his condition. I am writing to document my patient’s medical history and diagnosis and to summarize my treatment rationale. Treatment with Natesto is medically appropriate and necessary for this patient.

[Patient’s name] is [a/an] [age]-year-old male who was diagnosed with [testosterone deficiency/hypogonadism] on [date]. [Patient’s name] has been in my care since [date], and his condition is causing symptoms of [erectile dysfunction/decreased libido/weight gain/increased body mass/insomnia/metabolic syndrome/insulin resistance/changes in mood/cognitive impairment/gynecomastia/decreased muscle mass/osteoporosis].

[If Prior TTh: This patient has been on testosterone therapy [prior testosterone therapy] since [date] [if polycythemia is a concern, add: and his latest HCT was [enter HCT].]

[For Fertility Maintenance Naïve to TTh: In addition, this patient has expressed a desire to try to maintain his fertility. His current total sperm count and total motile sperm count are [count 3, count 4], documented on [date]. Due to the short-acting nature of Natesto and the decreased effect on spermatogenesis suppression reported\* with Natesto, I have further reason to believe that Natesto is an appropriate treatment for my patient.]

[For Fertility Maintenance Prior TTh: In addition, this patient has expressed a desire to try to [maintain/regain] his fertility. Before starting testosterone therapy with [prior testosterone therapy] on [date], his total sperm count and total motile sperm count were [count 1, count 2], documented on [date], and his current total sperm count and total motile sperm count are [count 3, count 4], documented on [date]. Due to the short-acting nature of Natesto and the decreased effect on spermatogenesis suppression reported\* with Natesto, I have further reason to believe that Natesto is an appropriate treatment for my patient.]

[For Polycythemia Naïve to TTh: In addition, this patient [has been diagnosed with/is at risk of developing] [polycythemia/erythrocytosis] and presents with a clinical history of [elevated HCT/sleep apnea/past or current smoker/COPD/obesity]. Clinical studies have shown that the risk of developing polycythemia in patients using Natesto is low.]

[For Polycythemia Prior TTh: In addition, this patient [has been diagnosed with/is at risk of developing] [polycythemia/erythrocytosis] and presents with a clinical history of [elevated HCT/sleep apnea/past or current smoker/COPD/obesity]. Clinical studies have shown that the risk of developing polycythemia in patients using Natesto is low.]

[List any previous and current therapies/procedures, responses to those interventions, and a description of the patient’s medical history and recent symptoms. Use medical judgment and discretion when providing a description of the patient’s medical condition, including how current symptoms may be impacting his daily life.]

Considering my patient’s history and condition, the Full Prescribing Information supports the use of Natesto. I believe treatment with Natesto is appropriate, medically necessary, and should be covered and reimbursed. Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [physician’s phone number] for any additional information you may require. Given the urgency of [patient’s name]’s condition, I look forward to your timely approval.

Sincerely,

[Physician’s signature] [Physician’s name]

[Suggested enclosures:

Package insert for Natesto

Copy of patient medical records

Other supporting documentation]

\*Primary outcome from a phase 4, single-site, open-label, single-arm clinical trial (N=60).1

**Reference: 1.** Data on file. Acerus Pharmaceuticals Corporation.

NAT-US-0116 07/21